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AND SRI LANKA

June 23, 2020

VIA E-MAIL

The Honorable Robert B. Kugler
United States District Judge
District of New Jersey

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on June 24.

1. Plaintiff Fact Sheets

The parties held a meet and confer on June 22, 2020, and Defendants believe they have reached a general consensus on most, but not all, of this process. Plaintiffs have asked Defendants for additional information, such as a list with the complete contact information for the attorneys signing individual deficiency notices, which Defendants have agreed to provide.

In addition to providing contact information for Defendants, and continuing to meet and confer with any individual counsel who will respond to the deficiency letter, Defendants have offered to set regular M&C times on a weekly or biweekly basis to speak with individual Plaintiff's counsel or liaison counsel as needed. Defendants also believe the parties are in agreement that a show cause order may be entered over the next few weeks, ordering the listed Plaintiffs who have

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appeared on two consecutive agenda lists to appear at the July CMC and show cause as to why their cases should not be dismissed with prejudice. Defendants have agreed they will continue to meet and confer with individual Plaintiff's counsel in the interim and will withdraw the show cause request with respect to any Plaintiff who cures their core deficiencies.

The current disconnect with Plaintiffs' liaison counsel is that Defendants do not believe a separate argument before the Court at the mid-month discovery teleconference on individual Plaintiff's Fact Sheet deficiencies is necessary before the order to show cause is issued. To the extent Plaintiffs wish to raise larger objections to categories of core deficiencies or other "macro-type" issues—like the two items Defendants brought to the Court's attention regarding the form of authorizations and some Plaintiffs refusing to provide an estimate of medical expenses—these issues can properly be argued to the Court and resolved as a separate agenda item at upcoming teleconferences. However, there is no need for the Court to hear two separate arguments on each and every individualized PFS deficiency: (1) whether the alleged deficiency justifies entry of a show cause order; and (2) whether Plaintiffs have shown good cause with respect to said deficiency.

Defendants believe the text and intent of the process approved by the court in CMO-16 and adopted from Benicar contemplates that the parties will meet and confer, and if the PFS deficiency dispute is unresolved after a Plaintiff has received a deficiency notice and been listed on the agenda for two CMCs, Defendants will request an order to show cause as to that Plaintiff. Thereafter, the parties may still continue to meet and confer, and if the dispute is not resolved Plaintiff's counsel will be required to appear—once—at the next CMC in response to the show cause order, at which time the Court will hear argument on individual disputes as needed.

To facilitate this process, Defendants propose that, as requested by Plaintiffs' counsel, an updated list of deficient cases, further revising the agenda list attached as Exhibit A will be provided to Plaintiffs by June 29, 2020. By July 6, 2020, Defendants will request a show cause order returnable at the July CMC as to any cases with unresolved deficiencies. Defendants have committed that they will continue to meet and confer prior to the July CMC, and the parties may address any overarching disputes by listing them as agenda items on the mid-month teleconference. However, there is no need nor basis for a separate argument prior to Defendants requesting and the Court entering a show cause order.

2. Manufacturer Sales and Pricing Productions

ZHP and Solco

ZHP and Solco believe they have reached an agreement with Plaintiffs to continue to meet and confer regarding certain requests relating to ZHP and Solco's sales and pricing information, as set forth below.

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After months of negotiations, the Court approved one document request, with five sub-parts, regarding the Manufacturer Defendants' sales and pricing. That request ("Doc. Req. 107"), requires the Manufacturer Defendants to produce:

[D]ocuments sufficient to show (i) the customers to whom you sold valsartan API or valsartan finished dose, (ii) unique identifiers for product sold (e.g., lot number, batch number, NDC code, etc.), (iii) quantities of valsartan API or valsartan finished dose sold, (iv) dates of sale, and (v) net and gross price per sale.

ECF 328 at pdf page 16 (emphasis added).

Solco produced sales and pricing information sufficient to show the information sought by Doc. Req. 107 by June 2, 2020.¹ As agreed to during the preliminary Court conference on sales and pricing on June 3, 2020, ZHP intends to supplement its earlier sales and pricing productions, dated May 15 and June 2, with its production of hard copy invoices (for sales of API) and purchase orders (for sales of finished dose to Solco) by July 6, 2020, thereby completing its production of the information sought by Doc. Req. 107.

Notwithstanding that during the June 3 conference Plaintiffs focused on just two issues regarding ZHP and Solco's sales and pricing information, on June 8, 2020, Plaintiffs sent ZHP and Solco a twelve-page letter containing ***more than 130 questions***. See Ex. B.² While some of these questions sought clarity about documents ZHP and Solco have produced or intended to produce, many of these were new requests seeking information about core discovery already produced or about Solco's data systems, despite there being no dispute that Solco produced electronic transactional sales data for each sale of valsartan. ZHP and Solco have expressed to the Court, see ECF No. 477, and Plaintiffs their view that the letter is overreaching and harassing, and an improper attempt to exploit the meet and confer process. Nevertheless, ZHP and Solco also have already responded to ***at least 60*** of the questions, and have agreed to follow up with answers to ***at least another ten***. See Exs. C & D (answering questions regarding dates of sales, interaction

¹ Solco's Sales Spreadsheet (SOLCO00005386) includes for each sale of valsartan finished dose on a transactional basis: (i) customer, (ii) unique identifier (both NDC and lot number), (iii) quantity, (iv) date, and (v) gross price per sale. The only portion of Doc. Req. 107 not included in that spreadsheet is net price per sale, because that is not something that Solco tracks (or could possibly track) on a transaction-by-transaction basis in the ordinary course of business. To try to respond in good faith to the portion of the document request seeking net sales, and given Plaintiffs' representation that they would accept aggregate data, Solco produced a spreadsheet that shows on an annual basis for each valsartan finished dose product sold, the step by step figures to go from gross to net income (SOLCO00005387).

² Herein, Plaintiffs' June 8, 2020 letter will be referred to as Exhibit B. Because Exhibits B-E contain content designated RESTRICTED CONFIDENTIAL, they will not be filed on the public docket, but will instead be sent in a confidential email submission to the Court for reference.

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between Solco's sales and pricing productions and productions in core discovery, and questions regarding fields in multiple spreadsheets).

On June 22, 2020, counsel for the parties held a telephonic meet and confer in which counsel for ZHP and Solco explained the burdensome nature of Plaintiffs' requests, especially given their focus on information in China, and requested that Plaintiffs demonstrate a need for the additional information requested by their letter, or make an attempt at narrowing their requests for that information so that the parties could meet and confer about additional information ZHP and Solco might produce. Accordingly, Plaintiffs sent a letter to ZHP and Solco on the evening of June 22, *see* Ex. E, which purports to revise certain of the requests set forth in Plaintiffs' letter dated June 8. Counsel for ZHP and Solco intend to carefully evaluate Plaintiffs' most recent letter, discuss it with their clients, and meet and confer with Plaintiffs about it.

Last week, the Court stated that it would attempt to resolve ripe sales and pricing issues this week, but if the defendant has not had time to respond or get its ducks in a row, then the issue will be reserved for resolution, if necessary, in July. 6/17/20 Tr. at 44:12-17 ("If the issue is premature and the defendants don't have an adequate time to respond or get their ducks in order, we won't decide the issue").³ Currently, there is no ripe issue. With their letter dated June 22, Plaintiffs have only just attempted to close the gap between their original 130+ requests and the approximately 70 requests to which ZHP and Solco have agreed to respond. ZHP and Solco have not had adequate time to evaluate Plaintiffs' revised requests in order to determine how to respond. The parties should continue to meet and confer to hopefully reach agreement before the end of July conference.

Mylan Defendants

In accordance with the Court's Order of April 20, 2020, Dkt. 416, Mylan made its initial production of sales and pricing documents on May 15. Since that time, Mylan has engaged in the meet-and-confer process with members of Plaintiffs' leadership group. Pursuant to those discussions, Mylan served a supplemental production of documents earlier today. Mylan believes that, with the provision of these materials, Mylan has largely complied with Plaintiffs' requests. However, should Plaintiffs seek additional information, Mylan will continue to participate in the meet-and-confer process in good faith to address Plaintiffs' concerns.

³ After the June 3, 2020, preliminary conference on sales and pricing issues, the Court instructed the parties that the "meet and confer discussions regarding the sales and pricing documents to be produced shall continue before and after July 6 [the date of ZHP's supplemental production]," and that any "future disputes regarding this topic will be addressed at the mid or late July conference." June 3, 2020 email from Judge Schneider. During the June 17, 2020 conference, the Court clarified its intention that any sales and pricing disputes will be addressed "at the late July conference." 6/17/20 Tr. at 7:21-8:1.

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3. Plaintiffs' Requests for Exemplar Transactional Documents

Separate from Doc. Req. 107, Plaintiffs have also requested what they deem to be "exemplar" documents that correspond with valsartan sales, such as invoices and purchase orders.

ZHP and Solco

On June 15, 2020, counsel for Plaintiffs sent counsel for ZHP and Solco Plaintiffs' request for exemplars. On June 17, 2020, counsel for ZHP and Solco responded, asking a clarifying question, which was never answered. On June 22, 2020, counsel for ZHP and Solco requested a telephonic meet and confer regarding Plaintiffs' requests. That conference took place today, June 23. During that conference, counsel for ZHP and Solco explained that, as regards product identification/tracing, Solco's core discovery and sales and pricing document productions already allow Plaintiffs to track which ZHP API batch was used to make which ZHP finished dose lot and which ZHP finished dose lot Solco sold to which of its customers. Nevertheless, Solco agreed to produce on a rolling basis examples of purchase orders and invoices for sales of finished dose valsartan to two wholesalers and two retailers.

Teva Defendants

Counsel for the Teva Defendants ("Teva") engaged in a meet and confer with Plaintiffs' counsel on Monday, June 15, 2020. At that time, Plaintiffs' counsel asked whether Teva would be able to produce exemplar documents kept in the ordinary course of business including (1) invoices and/or purchase orders between Teva and its customers and (2) documents included in the shipment of finished dose valsartan between Teva and its customers. On Monday, June 22, 2020, counsel for Teva informed Plaintiffs' counsel that it hopes to provide more information about what types documents Teva would be able to provide by the end of this week.

4. Downstream Defendants

Pursuant to the extension of the deadline for plaintiffs' reply in support of their letter brief on macro-discovery issues, the macro-discovery issues regarding downstream defendants will be taken up at the teleconference scheduled with the Court and the parties on July 6, 2020, at 1:30 pm. Other than the plaintiffs' fact sheet/show cause process issue that affects all defendants, there are no agenda items for the June 24, 2020, conference specific to the Retailer defendants, and plaintiffs and the Retailer defendants have not conferred regarding any specific agenda items for the conference.

Wholesaler defendants met and conferred with plaintiffs' counsel on June 23, 2020, regarding plaintiffs' request for "exemplar documents." "Exemplar documents" are the subject of plaintiffs' yet to be finalized requests for production numbers 6 and 8 in plaintiffs' Second Amended Requests for Production of Documents to Wholesaler Defendants, (See Dkt. No. 413-3). The meet and confer was purportedly to discuss accommodating Plaintiffs' counsel with an early potential production of a certain subset of "exemplar documents" in connection with similar

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“exemplar documents” recently produced by manufacturer defendants and which Plaintiffs sought prior to the service of the finalized negotiated RFPs. While discussing the “exemplar documents” received from manufacturers and the subset of “exemplar documents” plaintiffs currently seek on an expedited basis from Wholesaler defendants, plaintiffs’ counsel announced for the first time that plaintiffs may seek to add a new RFP never discussed and certainly not briefed - production of copies of all shipment documents for Wholesaler transactions with manufacturers and retailers for an eight year time period. This request has never been made of Wholesalers, there has never been a meet and confer regarding such a request, the issue has never been raised as a “macro” issue, the issue has never appeared on an agenda to the Court and the request and burden related thereto has certainly never been briefed. Wholesaler defendants object to any attempt by plaintiffs to suggest that the issue of production of such documents is a matter before the Court or ripe for discussion with the Court.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs’ Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants’ Counsel*)
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